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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,147	08/22/2003	Robert E. Fischell	A4-03	7169

7590 05/18/2005  
Dr. Robert E. Fischell  
14600 Viburnum Drive  
Dayton, MD 21036

EXAMINER

FAULCON JR, LENWOOD

ART UNIT PAPER NUMBER

3762

DATE MAILED: 05/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/645,147

Applicant(s)

FISCHELL, ROBERT E.

Examiner

Lenwood Faulcon, Jr.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 August 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Claim Objections***

1. Claim 8 is objected to because of the following informalities: claim 8 states "implanted pacemaker of defibrillator;" however, Examiner believes Applicant intended it to read "implanted pacemaker or defibrillator." Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (U.S. Patent No. 5,135,004) in view of Mishkin (U.S. Patent No. 5,902,336).

Adams et al. teaches of an apparatus and monitoring for assisting in diagnosis of myocardial ischemia (col. 2 lines 16-18) and using the apparatus on a patient who has previously suffered a myocardial infarction (col. 1 lines 32-35 and 56-66). Adams et al. further teaches that the apparatus is an implantable myocardial ischemia monitor that is capable of detecting ST segment shifts in a patient electrogram and providing an audio alarm to warn a patient of a potential myocardial infarction episode before one occurs (col. 6 lines 43-61). Adams et al. also teaches that the microprocessor that is coupled to the alarm (col. 6 lines 43-45) also transmits stored data to an external receiver for readout by the physician (col. 6 lines 33-42). It is inherent that the physician would

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have the ability to have voice communication with his or her patient, especially if the system's alarm is triggered.

Mishkin teaches of an implantable device and method for removing fluid from the blood of a patient who is experiencing renal failure (col. 1 lines 61-64). Mishkin teaches that leading causes of death in patients with End Stage Renal Disease is cardiac related, which may include acute myocardial infarction (col. 1 lines 12-16). Mishkin further teaches that patients who suffer from End Stage Renal Disease are those likely to be connected to a dialysis system (col. 1 lines 23-27). Mishkin also teaches of the device having monitoring capabilities (col. 7 lines 14-15)

It would have been obvious to one having ordinary skill in the art at the time of the invention to combine the teachings of Adams et al. with the teaching of Mishkin to have an implantable device that warns a patient who suffers from End Stage Renal Disease of potential acute myocardial infarctions. Adams et al. and Mishkin both teach of implantable medical devices that have monitoring capabilities, and thus teach of analogous arts. It would have been obvious to one having ordinary skill in the art at the time of the invention to use the device as taught by Adams et al. on a patient who suffers from End Stage Renal Disease since the patient is likely to suffer from a cardiac related disease such as acute myocardial infarction, as taught by Mishkin (col. lines 12-16). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the teachings of Adams et al. with the teachings of Mishkin to have the limitations of claims 1-4.

3. Claims 5-6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (U.S. Patent No. 5,135,004) in view of Mishkin (U.S. Patent No. 5,902,336) as applied to claims 1-4 above, and further in view of Bardy (U.S. Patent No. 6,336,903).

Bardy teaches of an automated system and method for diagnosing and monitoring congestive heart failure, in which a patient's measured cardiovascular information can be obtained by an implantable medical device, such as a cardiovascular monitor or therapeutic device (col. 3 lines 17-25). Bardy further teaches of the system comprising a database that stores patient care records, which includes information on the patient's medical history (col. 6 lines 65-67, col. 7 lines 1-3) that can be obtained through a patient interview or questionnaire (col. 7 lines 29-36).

It would have been obvious to one having ordinary skill in the art at the time of the invention to combine the teachings of Adams et al. and Mishkin as applied above, with the teachings of Bardy to have a method of using an implantable device that alerts a dialysis patient of a potential acute myocardial infarction and further obtaining information about the patient's medical history. Adams et al., Mishkin and Bardy all teach of implantable medical devices that have monitoring capabilities, and thus teach of analogous arts. It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the apparatus and monitor as taught by Adams et al. by determining if a patient is a dialysis patient when implanting a medical device that is capable of warning the patient of a potential acute myocardial infarction, since Adams et al. suggests having past medical information about a patient (col. 1 lines 32-35 and 56-

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66) and such information that could be indicative of a potential acute myocardial infarction includes dialysis patient who suffer from end state renal disease as suggested by Mishkin (col. 1 lines 12-16).

It would have also been obvious to one having ordinary skill in the art at the time of the invention that a physician would modify the methods as taught by Adams et al. to include in the medical history from patient information about various health problems and treatments such as whether the patient is a diabetic and/or has suffered from a previous heart attack, and whether the patient has an implanted pacemaker or defibrillator in order to provide efficient and safe health care. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the teachings of Adams et al., Mishkin and Bardy to meet the limitations of claims 5-6 and 8.

### ***Conclusion***

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Segalowitz (U.S. Patent No. 5,511,553), Benser (U.S. Patent No. 6,108,577), Fischell et al. (U.S. Patent No. 6,112,116), Fischell et al. (U.S. Patent No. 6,272,379), Stadler et al. (U.S. Patent No. 6,324,421), Bardy (U.S. Patent No. 6,368,284), Stadler et al. (U.S. Patent No. 6,381,493).


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lenwood Faulcon, Jr. whose telephone number is 571-272-6090. The examiner can normally be reached on Monday-Thursday from 9 to 5 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes, can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Lenwood Faulcon, Jr.

  
George Manuel  
Primary Examiner